K012803

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Appendix E

510(K) SUMMARY
AL-2000 Combined Biometer and Pachymeter

This 510(K) summary of safety and effectiveness for the combined biometer and pachymeter is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(K) summary.

Applicant: Tomey Corporation USA

Address: 300 Second Avenue
Waltham, MA 02451

Contact Person: Leslie C.M. Amodei
General Manager

Telephone: 781-890-1515
781-290-5885 (fax)

Preparation Date: August, 2001
(of the Summary)

Device Name: AL-2000 Combined Biometer and Pachymeter

Common Name: Biometer and Pachymeter

Classification Name: System, Imaging, Pulsed Echo, Ultrasonic
(see: 21 CFR 892.1560). Product Code: IYO. Panel: 90.

Legally marketed predicate devices: Compuscan LT Biometric Ruler and IOL Calculator (K910956)
DGH-4000 A-Scan Pachymeter (K913067A)

Description of the Device: The AL-2000 is an ultrasound instrument designed for measuring the axial length of the eye and the thickness of the cornea for ophthalmic use.

Ultrasound energy is emitted from the probe tip. The probe acts as both the transmitter and receiver of ultrasound energy. Some of the energy is reflected back toward the probe in the form of an echo. Measurement data can be calculated based on both the time it takes the echo to travel back to the probe from the eye and the preset converted velocity.

The instrument provides five types of standard IOL power calculations, which can be made immediately after measuring the axial length.

The instrument uses measured (or entered) axial length and entered corneal curvature, desired postoperative refraction and lens constant values to calculate IOL power.

Indications for Use:

The AL-2000 is indicated for:

- The axial length measurement of the eye by ultrasonic means;
- The implanted IOL power calculation, using the axial length measurement;
- Measurement of the corneal thickness before, during and after corneal and refractive surgery; for corneal disease assessment; and for contact lens fitting.

Comparison to: The specifications of the AL-2000 are the same or very similar to those of the claimed predicates.

Performance Data: None. The specifications and indications for use of the AL-2000 Combined Biometer and Pachymeter are the same or very similar to those of the claimed predicate devices. The AL-2000 has the same indications for use for which the claimed predicates have been cleared and has no additional indications for use.

Because of this, performance data were not required.

Conclusion: Based on the foregoing, Tomey believes that the AL-2000 is substantially equivalent to legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 8 2002

Tomey Corporation Japan
% Ms. Maureen O'Connell
Regulatory Consultant
Tomey Corporation, USA
5 Timber Lane
NORTH READING MA 01864

Re: K012803
Trade Name: AL-2000 Combined Biometer and Pachymeter
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: 90 IYO
Dated: March 7, 2002
Received: March 8, 2002

Dear Ms O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the AL-2000 Combined Biometer and Pachymeter, as described in your premarket notification:

Transducer Model Number

Biometer 10 MHz
Pachymeter 20 MHz

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801, please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97).

Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

If you have any questions regarding the content of this letter, please contact Rodrigo C. Perez at (301) 594-1212.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications for Use Form

System:_____ **Transducer:** **Pachymeter 20 MHz**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012813

Diagnostic Ultrasound Indications for Use Form

System:AL-2000 **Transducer:**_____

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

✓ Prescription Use (Per 21 CFR 801.109)

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012803

Diagnostic Ultrasound Indications for Use Form

System:_____ **Transducer: Biometer 10 MHz**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined	Other (specify)
Ophthalmic	N									
Fetal										
Abdominal										
Intraoperative										
Intraoperative Neurological										
Pediatric										
Small Organ										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N=new indication; P=previously cleared by FDA; E=added under Appendix E

Additional Comments:_____

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✓ Prescription Use (Per 21 CFR 801.109)

Nancy C Brogdon

(Division Sign-Off)
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510(k) Number K012803